

K102349

**510(k) Summary**  
as required by 807.92

NOV 24 2010

**1. Company Identification**

Konica Minolta Medical & Graphic, Inc.  
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan  
Establishment Registration Number: 3004485675

**2. Submitter's Name and Address**

Shigeyuki Kojima  
Manager  
Regulations and Standards Section, Quality Assurance Center  
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan  
Telephone: 81-42-589-8429  
Fax: 81-42-589-8053

**3. Date of Submission**

August 11, 2010

**4. Device Trade Name**

AeroDR SYSTEM

**5. Common Name**

Digital Radiography

**6. Classification, Product Code**

Class II, 21 CFR 892.1650, 90MQB and 21 CFR 892.2050, 90LLZ

**7. Predicate Device**

Carestream DRX-1 System, K090318  
KONICAMINOLTA, FlexDR C30, K082347

**8. Device Description**

The AeroDR SYSTEM is a digital imaging system to be used with diagnostic x-ray systems. It consists of AeroDR Detector (flat panel digital detector), Console CS-7 (operator console), AeroDR Interface Unit, AeroDR Generator Interface Unit, AeroDR Access Point and AeroDR Battery Charger. Images captured with the flat panel digital detector can be communicated to the operator console via wired connection or wireless, depend on user's choice.

## **9. Indications for Use**

The AeroDR SYSTEM is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. The AeroDR SYSTEM is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

## **10. Substantial Equivalence to Predicate Device**

The predicate device and the AeroDR SYSTEM are the same digital imaging systems.

The Indications for Use of this new device and predicate devices are almost identical. The detector of the new device is FPD (Flat Panel Detector) with scintillator of Cesium Iodide (CsI). The detector type of this new device and predicate device are the same. The principals of operation and technological characteristics of this new device and predicate devices are similar. The results of performance testing shows that there is no new safety and efficacy issue of The AeroDR SYSTEM introducing those already have identified with the predicate device.

## **11. Safety Information**

The AeroDR SYSTEM has been tested and shown to meet the requirements of IEC 60601-1 and IEC 60601-1-2.

The Risk Analysis for the AeroDR System was conducted on the basis of ISO14971, "Medical devices – Application of risk management to medical devices". As a result of risk control measures, the risk associated with all of the identified hazards was reduced to an acceptable level.

## **12. Conclusion**

Comprehensively, we judged that the AeroDR System has the same technological characteristics as the predicate devices. This 510(k) has demonstrated substantial equivalence as the predicate devices.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Konica Minolta Medical & Graphic, Inc.  
% Mr. Russell Munves  
Official Correspondent  
Storch, Amini, & Munves, P.C.  
140 E. 45<sup>th</sup> Street, 25<sup>th</sup> Floor  
Two Grand Central Tower  
NEW YORK NY 10017

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

AUG - 9 2013

Re: K102349

Trade/Device Name: AeroDR SYSTEM  
Regulation Number: 21 CFR 872.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: KPR  
Dated: October 8, 2010  
Received: October 12, 2010

Dear Mr. Munves:

This letter corrects our substantially equivalent letter of November 24, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

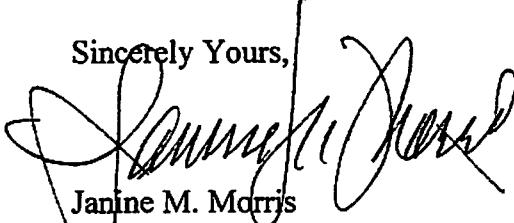
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

NOV 24 2010

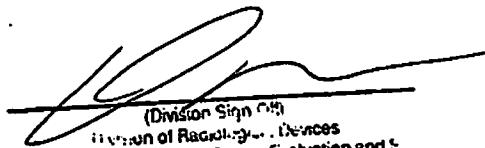
510(k) Number (if known) : K102349

Device Name : AeroDR SYSTEM

### Indications for Use:

The AeroDR SYSTEM is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures.

The AeroDR SYSTEM is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

  
11/24/10  
(Division Sign ODE)  
Division of Radiological Devices  
and Diagnostic Device Evaluation and  
K102349

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)